

DBV Technologies Announces FDA Acceptance of BLA filing for Viaskin Peanut for the Treatment of Peanut Allergy

If approved, Viaskin Peanut would be the first and only epicutaneous immunotherapy indicated for this potentially life-threatening condition in children

DBV Technologies, (Euronext: DBV - ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), a clinical-stage biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the Biologics License Application (BLA) for its investigational Viaskin® Peanut immunotherapy for the treatment of peanut-allergic children ages 4 to 11 years. Viaskin Peanut is the Company's lead product candidate designed to potentially reduce the risk of life-threatening allergic reactions due to accidental exposure to peanuts. A non-invasive, once-daily, epicutaneous patch, Viaskin Peanut seeks to deliver microgram quantities of peanut antigen to activate the immune system. Viaskin Peanut is based on investigational epicutaneous immunotherapy (EPIT®), DBV's proprietary method of delivering biologically active compounds to the immune system through intact skin.

"The acceptance of the Viaskin Peanut BLA is a meaningful step forward for peanut-allergic patients and their families," stated Daniel Tassé, Chief Executive Officer of DBV Technologies. "We commend the tireless efforts of the DBV team, the investigators and the more than 1,000 patients living with peanut allergies who participated in our clinical trials and made this milestone possible. We know children and their families are seeking a safe and effective treatment that may fit into their daily lives. We look forward to continuing to work with the FDA to potentially bring Viaskin Peanut to patients in the second half of 2020."

The target action date provided by the FDA is August 5, 2020. The FDA has communicated that it is currently planning to hold an advisory committee meeting to discuss the Viaskin Peanut application. Viaskin Peanut received Breakthrough and Fast Track Designation from the FDA in 2015 and 2012, respectively.

The BLA for Viaskin Peanut is supported by a global development program comprised of eight clinical trials including two Phase I clinical trials, four Phase II clinical trials, and two Phase III clinical trials (PEPITES and REALISE).

The FDA's acceptance of the Viaskin Peanut BLA submitted on August 6, 2019 follows the December 2018 withdrawal of the Company's previously submitted BLA.



Viaskin Peanut has not been approved for marketing by the U.S. Food and Drug Administration (FDA) or any other health authority. The safety and efficacy of Viaskin Peanut have not been evaluated by the FDA or any other health authority.

About DBV Technologies

DBV Technologies is developing Viaskin[®], an investigational proprietary technology platform with broad potential applications in immunotherapy. Viaskin is based on epicutaneous immunotherapy, or EPIT[®], DBV's method of delivering biologically active compounds to the immune system through intact skin. With this new class of self-administered and non-invasive product candidates, the Company is dedicated to safely transforming the care of food allergic patients, for whom there are no approved treatments. DBV's food allergies programs include ongoing clinical trials of Viaskin Peanut and Viaskin Milk, and preclinical development of Viaskin Egg. DBV is also pursuing a human proof-of-concept clinical study of Viaskin Milk for the treatment of Eosinophilic Esophagitis, and exploring potential applications of its platform in vaccines and other immune diseases. DBV Technologies has global headquarters in Montrouge, France and offices in Bagneux, France, and North American operations in Summit, NJ and New York, NY. The Company's ordinary shares are traded on segment B of Euronext Paris (Ticker: DBV, ISIN code: FR0010417345), part of the SBF120 index, and the Company's ADSs (each representing one-half of one ordinary share) are traded on the Nasdaq Global Select Market (Ticker: DBVT).

Forward Looking Statements

This press release may contain forward-looking statements and estimates, including statements regarding the potential of the EPIT platform and Viaskin[®] Peanut as a treatment for peanut-allergic children, and the Company's regulatory plans regarding Viaskin Peanut. These forward-looking statements and estimates are not promises or guarantees and involve substantial risks and uncertainties. At this stage, the products of the Company have not been authorized for sale in any country. Among the factors that could cause actual results to differ materially from those described or projected herein include uncertainties associated generally with research and development, clinical trials and related regulatory reviews and approvals and the risk that historical clinical results in one patient population may not be predictive of future clinical trial results in different patient populations. A further list and description of these risks, uncertainties and other risks can be found in the Company's regulatory filings with the French Autorité des Marchés



Financiers, the Company's Securities and Exchange Commission filings and reports, including in the Company's Annual Report on Form 20-F for the year ended December 31, 2018 and future filings and reports by the Company. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements and estimates, which speak only as of the date hereof. Other than as required by applicable law, DBV Technologies undertakes no obligation to update or revise the information contained in this Press Release.

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